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(54) Title: NON-INVASIVE IDENTIFICATION SYSTEM

(57) Abstract

A system and a kit for the non-invasive collection of DNA material from the inner cheeks of a living person or corpse. Included are swabs of high modulus fibers which scrape DNA material from the inner cheeks to obtain sufficient material for future identification.

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NON-INVASIVE IDENTIFICATION SYSTEM

Field of the Invention

The present invention provides an improved non-invasive system for generating a genetic file for identification and medical evaluation. More particularly, the present invention relates to the harvesting of cells for DNA isolation and genetic testing from the inner cheeks of individuals and corpses for the purpose of storage for later evaluation.

Background of the Invention

The ability of diagnose genetic disease has developed rapidly over the last 20 years. There are tests today which could reveal to some the likelihood of suffering in later life diseases to which they have a propensity. Disease conditions with currently available tests include cystic fibrosis, Huntington's disease, Gaucher's disease, hemophilia, retardation, sickle cell anemia, Down's syndrome, and others.

While many gene-based applications are being used today in the diagnosis and prognosis of diseases, it is the area of predisposition testing that will provide the shift to disease prediction.

Information from parents and grandparents is seldom collected and preserved for use in genetic testing. DNA (deoxyribonucleic acid) matching has been used to identify missing people both living and dead.

Therefore, there exists a need for an effective system of collecting and preserving vital identifying or hereditary information about cell bearing specimens from family members. Such a system should be complete, convenient, easy to use at home

without supervision and should be adapted to preserve cell bearing specimens for long periods of time without significant deterioration of the specimens.

U.S. Patent No. 5,101,970 to Turner discloses one system for collecting and storing DNA specimens from living persons which includes storage of the specimens together with information in a freezer. However, the information is collected only from living parties and blood samples are used.

DNA is responsible for transmitting a person's hereditary characteristics. PCR (Polymerase Chain Reaction) technology can amplify a genetic blueprint a million fold as tiny segments of the human genomic DNA. DNA samples can be obtained by swabbing or scraping the inside of a cheek with a sterile swab.

DNA samples taken from skin or hair may be tainted with chemicals from hair sprays or body lotions so as to obscure the DNA reading.

It is understood that the term "inner cheeks" which is used herein refers to the cheek area as well as the portion of the mouth about the lips and is referred to as the buccal mucosa.

Summary of the Invention

The present invention provides a method of collecting and storing DNA bearing materials from living or deceased persons. According to the present invention, a plurality of sterile swabs are used to collect the DNA bearing material from the inner cheeks of the person by stroking the inside of the cheeks at least about 10 times, preferably at least 20 times when unsupervised.

Advantageously, about 2250 nanograms of DNA bearing material is collected with each swab so as to obtain at least 4500 nanograms.

The DNA bearing swabs are then placed into an envelope which bears information regarding the donor of the DNA specimen. The specimens can then be sent for processing. The DNA inside of the cells on a swab are stable for over a month at room temperature and can experience extreme temperatures of 37°C and -20°C for 12 to 24 hour periods.

It is known that the presence of secretory leucocyte protease inhibitor in saliva reduces the chance of HIV infection so as to provide the use of inner cheek material as a safer method of evaluation for the technician than the use of blood samples.

Preferably, at least two or more, preferably 3-6 swabs of DNA material are collected for preservation or immediate processing. Advantageously, the envelopes containing the swabs with specimens are bar coded to preserve the confidentiality of the person and/or the party with whom the background information is applied.

In connection with the method of the present invention, there is provided a kit. The preferred kit contains an envelope with a data information sheet which identifies the party providing the specimens. A second envelope contains at least six sterile swabs. The swabs are of high modulus fibers. A third envelope or container is preaddressed to a depositary. Advantageously, the envelopes are bar coded so as to be read by a computer. The kit is provided so that the DNA material can be

collected at home.

It is therefore an object of the invention to provide a more efficient non-invasive method for collecting DNA samples from living or deceased persons at the time of death.

It is another object of the invention to improve the method for identifying missing or lost people.

It is yet another object of the invention to provide a safer method of evaluation by a technician of DNA material.

It is still another object of the invention to provide a genetic record which is complete even after a relative dies.

These and other objects, features, and advantages will become more apparent upon review of the following detailed description.

Detailed Description of the Preferred Embodiments

The present invention provides a non-invasive system for collecting and preserving data and physical evidence from a living or deceased individual for identification. More specifically, means is provided for collecting a DNA sample from the inner cheeks of an individual, identifying the person and then sending the sample to a depository where the information is collected and the DNA sample is dated, identified and/or stored in a frozen state for future use.

In the present system a sealable envelope is provided which contains a data collection sheet for recording information regarding the individual providing the samples. In a second envelope sterile swabs are provided for collecting specimens from the inner cheeks of the individual. The swabs comprise high modulus synthetic fibers such as polyamide, polyester, polyimide,

polyethylene, and the like. Most preferable are swabs comprising DACRON (trademark of E.I. DuPont). It is preferred to have a multiplicity of swabs, preferably about 6-10 swabs so that sufficient material is available for multiple analysis over a period of time or generations of individuals. At least 10 strokes or rubbings are utilized to collect the samples so as to provide an average of at least about 4500 nanograms of DNA material for living persons or corpses. A further envelope is used for mailing the information sheet and swabs to a processing and storage facility.

The used swabs are returned into the envelope and placed together with the first envelope containing the data sheet into a third envelope which is then mailed for processing at a depository for a reading and/or storage in a conventional manner.

The following chart represents a study performed on living individuals wherein the individuals were requested to stroke their inner cheeks with a DACRON swab so as to collect DNA material.

CHART I

COMPARISON OF THE NUMBER OF SCRAPES/BUCCAL SWAB DNA ISOLATION PROCEDURE

Individual	1 Scrape	10 Scrapes	20 Scrapes
K	200	4800	7100
C	5500	6000	7800
D	3800	7600	7200
M	4500	5600	6800
S	3600	6000	7300
A	2800	5300	5000
N	0	4800	5700
B	6000	5500	7000
De	6100	7400	9100
P	5400	5200	5000
J	5600	10200	12000
D'A	6500	7600	4800
Ka	4600	6700	8300
MG	2800	5300	2800
MT	1000	3000	5100
TOTAL	58400	91000	101000

Conclusions

1 Scrape : 58400/15 = 3893 ng/2 swabs = 1946 ng/swab
10 Scrapes: 91000/15 = 6067 ng/2 swabs = 3033 ng/swab
20 Scrapes: 101000/15 = 6733 ng/2 swabs = 3367 ng/swab

As seen in Chart I, one scrape of the swab yields on the average of about 2000 nanograms of DNA material. Ten scrapes result in the samples of DNA per swab of an average of about 3,000 nanograms of DNA samples. 20 scrapes did not improve the yield of collected DNA material. 10 scrapes has been found to consistently result in more than 4500 nanograms of DNA material from two swabs, even when performed by non-technicians.

The following chart shows a study wherein DNA material was collected from the inner cheeks of corpses with ten scrapes. The study involved 22 corpses wherein 21 corpses were pre-embalmed and one was post-embalmed. All samples were collected 6-38 hours post mortem.

CHART II

POST-MORTEM SWAB SAMPLES

Sample	Pre-embalmed:			Post-embalmed:
1	1660	2930	1750	900
2	1800	1660	1980	615
3	1400	1480	2390	150
4	2250	1330	3020	
5	2050	1500	1660	1665/3=588 ng
6	1850	1750	1475	
7	1950	1450	1430	
8	1650	1430	1665	
9	1500	1270	2410	
10	2075	1510	2340	
11	1640	2035	1580	
12	1280	2090	1040	
13	1950	2840	1665	
14	1840	1260	2035	
15	1750	1400	2090	
16	1820	1790	2080	
17	1220	2080	1510	
18	1020	2250	1450	
19	1250	2640	1660	
20	2140	1640	1850	
21	1850	1660	2105	
Total	35935	38495	39075	
Average	113505/63=1800 ng/swab			

Because of the lack of moisture it has been found that at least three swabs are preferred to consistently obtain at least 4500 nanograms of DNA material. However, it was possible at times with only two swabs.

The Kit

The kit of the present invention is intended for use at home and by non-technicians. A container is provided which holds three envelopes. One envelope contains an information sheet or card which collects vital data used in identifying individuals such as name, address, place and date of birth, and relevant, medical history, etc. Such data can be used and is often valuable in identifying persons or relatives. If desired, means for fingerprinting and recording the fingerprints may be provided.

Another envelope is provided which contains the sterile swabs for obtaining the DNA material from the inner cheeks. The swabs can be in the form of a wrap of high modulus fibers on a stick that can be readily inserted to scrape the inner cheeks by the individual or other person. The used swabs can be reinserted into the envelope for proper identification and for sending up to storage facility.

The third envelope is a transporting or mailing envelope which preferably has the address of the storage facility. The identifying card in its envelope and the used swabs in their envelope can thereby be sent or mailed to the proper places.

Preferably, each of the envelopes is bar coded for easier identification that all of the envelopes are related. The envelopes should be of suitable material so as to permit writing and/or printing.

Sealable envelopes such as comprising TYVEK or plastic lined envelopes may be utilized.

With the vital information, the sealed envelopes can be sent to a processing laboratory where the DNA is removed and stored within a family freezer. In the freezer, the samples are chilled to a temperature below the freezing point so that the useful life of the samples can be extended.

At the depository, the bar coding from the envelope is placed on a computer system. The swab heads are cut from the swab stems and placed in microcentrifuge tubes where the DNA cells are lysed to extract DNA from the nuclei. The DNA is quantitated to assure a minimum amount of 4500 nanograms are present. This process insures the integrity of the DNA and that there is enough DNA for future testing. Preferably, the DNA samples are split and stored in two separate freezers for safety and integrity.

The invention has been disclosed above in terms of a preferred embodiment. It will be obvious that many variations of the illustrated embodiment might well be contemplated. The types of envelopes, container and the form of swabs may be varied to be in the form of tubes or boxes which can be cellulosic or of plastic materials. These and other modifications and additions might well be made to the illustrated embodiment without departing from the spirit and the scope of the invention as claimed.

What Is Claimed Is:

1. A method for the non-invasive collection of DNA from a living person or a corpse for storage and identification which comprises the steps of swabbing or scraping about the inner cheek of said person or corpse with at least two swabs consisting of high modulus fibers, each of said swabs scraping the inner cheek at least about ten times.

2. The method of claim 1 wherein each swab collects at least about 4500 nanograms of DNA material is collected.

3. The method of claim 1 wherein at least about 4500 nanograms of DNA are collected with three swabs from a corpse.

4. The method of claim 1 wherein at least 6 swabs are used.

5. The method of claim 1 wherein said high modulus fibers are selected from the group consisting of polyamide, polyethylene, terephthalate, polyimide and polyester.

6. The method of claim 1 including lysing of the DNA material from the swabs and storage of the lysed material at low temperatures.

7. The method of claim 1 wherein the collected DNA material contains secretory leucocyte protease inhibitor.

8. A kit for use in the non-invasive collection of DNA material from a living person or a corpse which comprises:

a first envelope suitable containing a data collection sheet;

a second envelope containing at least two swabs comprising high modulus fibers for collecting DNA material from inner cheeks;

a mailing envelope for mailing said data sheet and swabs to a storage facility, and a container for said envelopes.

9. The kit of claim 7 wherein at least six swabs are provided.

10. The kit of claim 6 wherein said envelopes are bar-coded.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 35/00
US CL :206/223; 604/1-3
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 53/440; 141/1; 206/223; 604/1-3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
Search Terms: specimen, idenification, bar cod?, dna, mai?

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	RICHARDS et al. Multiplex PCR amplification from the CFTR gene using DNA prepared from buccal brushes/swabs, Human Molecual Genetics, 1993, Vol. 2, No. 2 pgs 159-163, 1993 Oxford University Press, see entire document.	1, 2, 5-7 --- 3, 8-10
Y	US 5,101,970 A (TURNER) 07 April 1992, entire document.	8-10
Y	US 5,411,065 A (MEADOR et al) 02 May 1995, col. 17, lines 38-52.	10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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